

Remarks

The Office Action mailed October 7, 2005 has been carefully reviewed and the foregoing amendment has been made in consequence thereof.

Claims 1-89 are now pending in this application. Claims 1-118 stand rejected. Claims 90-118 have been cancelled.

In accordance with 37 C.F.R. 1.136(a), a three-month extension of time is submitted herewith to extend the due date of the response to the Office Action dated October 7, 2005, for the above-identified patent application from January 7, 2006, through and including April 7, 2006. In accordance with 37 C.F.R. 1.17(a)(3), authorization to charge a deposit account in the amount of \$1,020.00 to cover this extension of time request also is submitted herewith.

The rejection of Claims 1-30, 99-110 and 115-118 under 35 U.S.C. § 101 as being directed to non-statutory subject matter is respectfully traversed.

The Office Action asserts that "Claim 1 does not require any technology" and therefore is directed to non-statutory subject matter. Applicants respectfully traverse this assertion. However, Applicants have amended independent Claim 1. Applicants submit that the claims of the present patent application are directed to practical applications in the technological arts. "Any sequence of operational steps can constitute a process within the meaning of the Patent Act so long as it is part of the technological arts." In re Musgrave, 431 F.2d 882 (C.C.P.A. 1970). Moreover, Applicants submit that Claim 1 does recite certain technology. Claim 1 is therefore directed to a practical application in the technological arts.

Dependent Claims 2-30 depend from independent Claim 1, and these dependent Claims are submitted to satisfy the requirements of Section 101 for the same reasons set forth above with respect to independent Claim 1.

Claims 99-110 and 115-118 have been cancelled.

For at least the reasons set forth above, Applicants respectfully request that the Section 101 rejection of Claims 1-30, 99-110 and 115-118 be withdrawn.

The rejection of Claims 1-118 under 35 U.S.C. § 112, second paragraph, is respectfully traversed. Applicants respectfully submit that Claims 1-118 satisfy section 112, second paragraph. More specifically, Applicants respectfully submit that Claims 1-118 are definite and particularly point out and distinctly claim the subject matter of the invention. Applicants, however, have amended independent Claims 1, 31, 63 and 76. Applicants have also cancelled Claims 90-118. Accordingly, Applicants respectfully submit that Claims 1-89 are definite and particularly point out and distinctly claim the subject matter of the invention. For at least the reasons set forth above, Applicants respectfully request that the rejection of Claims 1-118 under 35 U.S.C. § 112, second paragraph, be withdrawn.

The rejection of Claims 1-118 under 35 U.S.C. § 102(e) as being anticipated by Swor et al. (U.S. Patent No. 6,148,297) ("Swor") is respectfully traversed.

Applicants respectfully submit that Swor does not describe or suggest the claimed invention. As discussed below, at least one of the differences between Swor and the present invention is that Swor does not describe or suggest a method for conducting a compliance risk assessment and mitigation process that includes storing in a database compliance information including at least one questionnaire relating to compliance, compliance requirements for each functional area within a business, and persons responsible for compliance within each functional area within the business, displaying a questionnaire on a client system associated with a person responsible for compliance with at least one functional area within the business, processing a response to the displayed questionnaire, and prioritizing compliance risks for the business including identifying compliance risks for each functional area within the business, and prioritizing the compliance risks from high to low based on a severity rating of non-compliance.

Moreover, Applicants submit that Swor does not describe or suggest identifying, for each compliance risk identified, potential compliance failure modes and potential causes and effects of such compliance failure modes, and calculating a risk prioritization number (RPN) for each compliance risk identified based on the data stored in the database wherein the RPN represents a relative compliance risk of a particular failure mode.

Furthermore, Applicants submit that Swor does not describe or suggest implementing risk monitoring and control mechanisms to mitigate compliance risks based on the calculated RPNs.

Swor describes an interactive system and method having at least two subsystems: one for providing exposure and incident information to a healthcare worker and another for collecting exposure and incident data at a healthcare facility in a confidential manner. The system includes input/output devices and a processor for accessing and displaying information on a desired healthcare topic and for collecting, via a series of interactive screens, accident data for subsequent collation within a facility and/or on a multifacility scale, such as for regulatory compliance. Data collection is preferably done in a confidential manner, and a report is generated that includes a risk assessment and recommended follow up procedures. The input/output devices are preferably located in close proximity to an area having a relatively high likelihood of exposures or incidents, for permitting the user ready access to desired information.

Claim 1 recites a method for conducting a consistent, documented and yet repeatable compliance risk assessment and mitigation process, using a network-based system including a server system coupled to a centralized database and at least one client system, the method includes "storing in the database compliance information including at least one questionnaire relating to compliance, compliance requirements for each functional area within a business, and persons responsible for compliance within each functional area within the business...displaying a questionnaire on a client system associated with a person responsible for compliance with at least one functional area within the business, the questionnaire is transmitted from the server system to the client system of the compliance person and is generated using the compliance information stored within the database...receiving at the server a response inputted by the compliance person to the displayed questionnaire...processing the response to the displayed questionnaire at the server...prioritizing compliance risks for the business including identifying compliance risks for each functional area within the business, and prioritizing the compliance risks from high to low based on a severity rating of non-compliance...identifying, for each compliance risk identified, potential compliance failure modes and potential causes and effects of such compliance failure modes...storing the risks, the risk priority, the failure modes, and the causes and effects in the database...calculating a risk prioritization number (RPN) for each compliance risk identified based on the data stored in the database, wherein the RPN represents a relative compliance risk of a particular failure mode...and implementing risk monitoring and control mechanisms to mitigate compliance risks based on the calculated RPNs."

Swor does not describe or suggest a method as recited in Claim 1. More specifically, Swor does not describe or suggest a method for conducting a compliance risk assessment and mitigation process that includes storing in a database compliance information including at least one questionnaire relating to compliance, compliance requirements for each functional area within a business, and persons responsible for compliance within each functional area within the business, displaying a questionnaire on a client system associated with a person responsible for compliance with at least one functional area within the business, processing a response to the displayed questionnaire, and prioritizing compliance risks for the business including identifying compliance risks for each functional area within the business, and prioritizing the compliance risks from high to low based on a severity rating of non-compliance.

Moreover, Swor does not describe or suggest identifying, for each compliance risk identified, potential compliance failure modes and potential causes and effects of such compliance failure modes, and calculating a risk prioritization number (RPN) for each compliance risk identified based on the data stored in the database wherein the RPN represents a relative compliance risk of a particular failure mode.

Furthermore, Swor does not describe or suggest implementing risk monitoring and control mechanisms to mitigate compliance risks based on the calculated RPNs.

Rather, Swor describes a health care information and data tracking system having at least two subsystems: one for providing exposure and incident information to a healthcare worker and another for collecting exposure and incident data at a healthcare facility in a confidential manner. Swor does not describe or suggest a method for conducting a compliance risk assessment and mitigation process as recited in Claim 1. For example, Swor does not describe or suggest calculating a risk prioritization number (RPN) for each compliance risk identified based on the data stored in the database wherein the RPN represents a relative compliance risk of a particular failure mode, and implementing risk monitoring and control mechanisms to mitigate compliance risks based on the calculated RPNs. Accordingly, Applicants respectfully submit that Claim 1 is patentable over Swor.

For at least the reasons as set forth above, Applicants respectfully request that the 35 U.S.C. § 102(e) rejection of Claim 1 be withdrawn.

Claims 2-30 depend from independent Claim 1 which is submitted to be in condition for allowance. When the recitations of Claims 2-30 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claims 2-30 are also patentable over Swor.

Claim 31 recites a system for identifying and quantifying compliance that includes at least one computer, a database for storing compliance information including at least one questionnaire relating to compliance, compliance requirements for each functional area within a business, and persons responsible for compliance within each functional area within the business, and a server, wherein the server is configured to "display a questionnaire on said computer associated with a person responsible for compliance with at least one functional area within the business, the questionnaire is transmitted from said server to said computer of the compliance person and is generated using the compliance information stored within the database...receive a response inputted by the compliance person to the displayed questionnaire...process the response to the displayed questionnaire...prioritize compliance risks for the business including identifying compliance risks for each functional area within the business, and prioritizing the compliance risks from high to low based on a severity rating of non-compliance...identify, for each compliance risk identified, potential compliance failure modes and potential causes and effects of such compliance failure modes...store the risks, the risk priority, the failure modes, and the causes and effects in the database...calculate a risk prioritization number (RPN) for each compliance risk identified based on the data stored in the database, wherein the RPN represents a relative compliance risk of a particular failure mode...and recommend risk monitoring and control mechanisms to mitigate compliance risks based on the calculated RPNs."

Claim 31, as herein amended, recites a system for identifying and quantifying compliance that includes a server configured to perform steps essentially similar to those recited in Claim 1. Thus, it is submitted that Claim 31 is patentable over Swor for reasons that correspond to those given with respect to Claim 1.

For at least the reasons as set forth above, Applicants respectfully request that the 35 U.S.C. § 102(e) rejection of Claim 31 be withdrawn.

Claims 32-62 depend from independent Claim 31 which is submitted to be in condition for allowance. When the recitations of Claims 32-62 are considered in combination with the recitations of Claim 31, Applicants submit that dependent Claims 32-62 are also patentable over Swor.

Claim 63 recites a computer programmed to "store in a database compliance information including at least one questionnaire relating to compliance, compliance requirements for each functional area within a business, and persons responsible for compliance within each functional area within the business...display a questionnaire for a person responsible for compliance with at least one functional area within the business, the questionnaire is generated using the compliance information stored within the database...receive a response inputted by the compliance person to the displayed questionnaire...process the response to the displayed questionnaire...prioritize compliance risks for the business including identifying compliance risks for each functional area within the business, and prioritizing the compliance risks from high to low based on a severity rating of non-compliance...identify, for each compliance risk identified, potential compliance failure modes and potential causes and effects of such compliance failure modes...store the risks, the risk priority, the failure modes, and the causes and effects in the database...calculate a risk prioritization number (RPN) for each compliance risk identified based on the data stored in the database, wherein the RPN represents a relative compliance risk of a particular failure mode...and recommend risk monitoring and control mechanisms to mitigate compliance risks based on the calculated RPNs."

Claim 63, as herein amended, recites a computer programmed to perform steps essentially similar to the steps recited in Claim 1. Thus, it is submitted that Claim 63 is patentable over Swor for reasons that correspond to those given with respect to Claim 1.

For at least the reasons as set forth above, Applicants respectfully request that the 35 U.S.C. § 102(e) rejection of Claim 63 be withdrawn.

Claims 64-75 depend from independent Claim 63 which is submitted to be in condition for allowance. When the recitations of Claims 64-75 are considered in combination with the recitations of Claim 63, Applicants submit that dependent Claims 64-75 are also patentable over Swor.

Claim 76 recites a computer program embodied on a computer readable medium for managing compliance risk assessment to enable businesses to develop broader and deeper coverage of compliance risks, using a network based system including a server system coupled to a centralized database and at least one client system, the computer program includes a code segment that "stores in the database compliance information including at least one questionnaire relating to compliance, compliance requirements for each functional area within a business, and persons responsible for compliance within each functional area within the business...displays a questionnaire on a client system associated with a person responsible for compliance with at least one functional area within the business, the questionnaire is transmitted from the server system to the client system of the compliance person and is generated using the compliance information stored within the database...receives a response inputted by the compliance person to the displayed questionnaire...processes the response to the displayed questionnaire at the server...prioritizes compliance risks for the business including identifying compliance risks for each functional area within the business, and prioritizing the compliance risks from high to low based on a severity rating of non-compliance...identifies, for each compliance risk identified, potential compliance failure modes and potential causes and effects of such compliance failure modes...stores the risks, the risk priority, the failure modes, and the causes and effects in the database...calculates a risk prioritization number (RPN) for each compliance risk identified based on the data stored in the database, wherein the RPN represents a relative compliance risk of a particular failure mode...and recommends risk monitoring and control mechanisms to mitigate compliance risks based on the calculated RPNs."

Claim 76 recites a computer program embodied on a computer readable medium that includes a code segment programmed to perform steps essentially similar to those recited in Claim 1. Thus, it is submitted that Claim 76 is patentable over Swor for reasons that correspond to those given with respect to Claim 1.

For at least the reasons as set forth above, Applicants respectfully request that the 35 U.S.C. § 102(e) rejection of Claim 76 be withdrawn.

Claims 77-89 depend from independent Claim 76 which is submitted to be in condition for allowance. When the recitations of Claims 77-89 are considered in combination with the

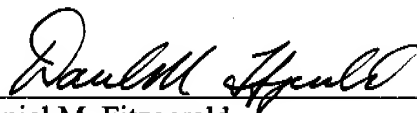
recitations of Claim 76, Applicants submit that dependent Claims 77-89 are also patentable over Swor.

Claims 90-118 have been cancelled.

For at least the reasons set forth above, Applicants respectfully request that the Section 102 rejection of Claims 1-118 be withdrawn.

In view of the foregoing amendments and remarks, all the claims now active in this application are believed to be in condition for allowance. Reconsideration and favorable action is respectfully solicited.

Respectfully Submitted,

A handwritten signature in cursive script, appearing to read "Daniel M. Fitzgerald", is written over a horizontal line.

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